Decision Memo for Electrodiagnostic Sensory Nerve Conduction Threshold (CAG-00106N)

Decision Summary

CMS concludes that the scientific and medical literature do not demonstrate that the use of sNCT to diagnose sensory neuropathies in Medicare beneficiaries is reasonable and necessary. Therefore, we intend to issue a national noncoverage decision.

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Decision Memo

To: Administrative File: CAG-00106N
Sensory Nerve Conduction Threshold Testing

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Subject: Coverage Decision Memorandum for Electrodiagnostic Sensory Nerve Conduction Threshold

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This decision memorandum addresses a request for a national coverage determination received from Neurotron. The service for which coverage is requested is electrodiagnostic sensory nerve conduction threshold (sNCT) to be used to diagnose sensory neuropathies, such as diabetic sensory neuropathies, uremic sensory neuropathies, and carpal tunnel syndrome. The memorandum serves four purposes: (1) gives a general overview of select measures to assess sensory nerve function; (2) reviews the history of Medicare's coverage policies regarding sensory nerve conduction threshold; (3) analyzes relevant scientific and clinical literature on the use of sensory nerve conduction threshold and its impact as a diagnostic device on patient management for patients with sensory neuropathies; and (4) delineates the reasoning for our intention to issue a noncoverage determination.

Clinical Background

The nervous system is composed of the brain, spinal cord, and peripheral nerves. One of the main functions of the nervous system is to collect sensory information. This information is then processed and interpreted in order to initiate appropriate responses throughout the body. A neuron is the basic structural unit of the nervous system. It is composed of a cell body and two types of processes, dendrites and axons. Neurons collect incoming (afferent) information through dendrites whereas axons conduct outgoing (efferent) signals away from the cell body. Nerve fibers are composed of bundles of axons held together by connective tissue.

Sensory nerves, which carry impulses from sensory receptors to the brain, are composed of one or more of the following three fibers: (1) small unmyelinated (C fibers) fibers conduct temperature and slow pain; (2) small myelinated (A delta fibers) fibers conduct pressure, temperature, and fast pain; and (3) large myelinated (A beta fibers) fibers conduct cutaneous touch and pressure.

Evaluating the function of sensory nerves may be of clinical importance for individuals who suffer from metabolic, hereditary, or acquired disorders, as well as those who have experienced a traumatic injury. There are several methods of evaluating sensory nerve function. Such tests include: (1) nerve conduction studies (NCS); (2) sensory nerve biopsy; and (3) sensory nerve conduction threshold (sNCT).[1] Of these, NCS is the most commonly used and widely-accepted diagnostic test.

NCS is used to measure action potentials resulting from peripheral nerve stimulation. It can help determine the diagnosis, severity, location, and distribution of a neuropathy and can assess the integrity of the axon and the myelin sheath (the insulation surrounding the axon). NCS can also detect dysfunction of both sensory and motor nerves. Typically, a nerve is stimulated with an electric shock at one location and a response is recorded at another location. Measurements include latency of response, conduction velocity, and amplitude of response. Of note, NCS primarily measures fast fibers. The test may cause mild discomfort from the shocks administered.

NCS is often performed in conjunction with electromyography (EMG). EMG is the study and recording or intrinsic electrical properties of skeletal muscles. It provides information on neuropathies, especially in detection of denervation of axonal neuropathy. EMG can help differentiate muscle wasting of neuropathic versus myopathic origin. It also aids in the differentiation of entrapment neuropathies versus proximal radicular compression. EMG involves the insertion of a needle directly into a muscle to record electrical activity. The procedure can be painful.

Sensory nerve biopsy provides information about the extent of both axonal degeneration and of segmental demyelination. Biopsies are performed on a cutaneous nerve, typically the sural nerve.

sNCT is non-invasive and typically conducted by technicians under the supervision of a physician. The test is performed by applying disposable surface electrodes on the skin of the patient. Three mild electrical stimuli are applied to a peripheral nerve. Measures are obtained using a portable, 6-V battery powered, microprocessor controlled, constant alternating current sinusoid waveform stimuli at intensities ranging from 0.01 mAmperes to 9.99 mAmperes and frequencies of 5 Hz, 250 Hz, and 2,000 Hz to, theoretically, assess the integrity of the three sensory nerve fiber types. The manufacturer asserts that abnormally high sNCT measures reportedly indicate a significant loss of nerve conduction, while abnormally low sNCT indicates a hyperesthetic state that corresponds with inflamed, irritated, or regenerating nerves. Typically, the procedure takes less than 30 minutes to complete.

Currently, there is only one sNCT device on the market, the Current Perception Threshold (CPT) by Neurotron. The CPT[2] uses the minimal amount of painless transcutaneous electrical stimulus required to reproducibly evoke a sensation.

FDA Status

Neurotron received FDA 510(k) clearance in 1986 to market the electrodiagnostic sensory Nerve Conduction Threshold (sNCT)/CPT Neurometer for the evaluation of sensory nerve diseases and injuries. The predicate device was vibratory end-organ tester.

History of Medicare's Coverage Policy on Sensory Nerve Conduction Threshold

Currently, Medicare does not have a national coverage determination with regard to the use of sNCT devices in the evaluation of sensory neuropathies. Because some Medicare contractors have implemented local medical review policies describing this service as noncovered, Neurotron has requested a national coverage decision relating to the use of sNCT devices.

The benefit category appropriate for the sNCT/CPT Neurometer is set forth in section 1861(s)(3) of the Social Security Act (i.e., sNCT is a diagnostic test).

Timeline of Activities

June 22, 2001	Neurotron requests a national coverage determination.
July 12, 2001	Neurotron meets with medical officer and policy analysts in the Centers for Medicare and Medicaid Services (CMS, formerly known as the Health Care Financing Administration).
November 16, 2001	Neurtron meets with CMS review team.

General Principles for the Evaluation of Diagnostic Tests

When CMS reviews a diagnostic test for a national coverage decision, among other things, it evaluates the clinical effectiveness of the test for the Medicare population. CMS considers the usefulness and effectiveness of the test on patient management. 42 C.F.R. § 410.32. An important consideration in this review is an assessment of the accuracy and technical characteristics of the test as compared to other diagnostic modalities. The optimal comparison is between the test under review and the gold standard, if one exists. Measures used to determine accuracy include sensitivity (probability of a positive test result in a patient with a disease) and specificity (the probability of a negative test result in a patient who does not have the disease). An increase in sensitivity does not necessarily mean that a test is more accurate. Specificity must be evaluated when determining if one test is more accurate than the other, because a highly specific test minimizes the number of false positive.[3] In addition, increasing sensitivity or specificity is often accomplished at the expense of the other. However, even though a diagnostic test may be very accurate, if the information provided by the test does not alter management of the condition, CMS may determine that the test is not used in the medical management for the specific condition.

Summary of Evidence

In determining the articles that would be eligible for review, we used the following inclusion and exclusion criteria:

Inclusion Criteria

1. Articles must be published in English language
2. Studies must have been conducted on human subjects
3. Studies must have enrolled at least 10 patients

Exclusion Criteria

1. Editorials
2. Abstracts
3. Review Articles
4. Published Letters/Comments

Using various combinations of the following search terms: "sensory nerve conduction" "neurometer" "current perception threshold," a total of ten studies were obtained. In addition, several articles were submitted for consideration by the manufacturer. The following represents a brief summary of the relevant studies.

Rendell (1989) compared NCS, CPT and vibration threshold (VT) as correlates of clinical severity of diabetic sensory neuropathy.[4] Seventy-one subjects with an average age of 52, who had a history of diabetes were recruited and subjected to sensory and motor NCS as well as CPT at 5, 250, and 2000 Hz of the upper and lower extremities. In addition, 28 of the 71 subjects had repeated evaluations at 2, 6, 10, and 12 months after the initial procedure. Each patient received a symptomatic score for the upper extremity and one for the lower extremity. The symptomatic score was obtained by asking the patient to describe his or her symptoms, which was then converted to a final grade by the examiner. Each patient also received a physical score that consisted of a neurological examination with an increased emphasis on the sensory portion of the examination. The sensory modalities assessed included light touch, pain, and thermal sensation. The symptomatic and physical scores were derived from the Neurological Symptom Score and the Neurological Disability Score proposed by Dyck for evaluating peripheral neuropathy. Spearman correlation coefficients between NCS, CPT, VT and the symptomatic and physical scores for the upper and lower extremities were calculated. Correlation coefficients of NCS with clinical scores were significant in most instances. The authors noted that coefficients of CPT with clinical scores appeared to be higher than for NCS in several instances. The authors also created a classification scheme for severity of symptoms. They reported that CPT was better at discriminating between severity classes than NCS. Data on clinical utility were not provided.

Weseley (1988) examined peripheral nerve integrity in 23 dialysis patients using CPT and NCS.[5] The median and peroneal nerves were selected and the tests were performed bilaterally. CPT was performed concurrently with dialysis. CPT and NCS measures were compared to previously established normative values. Grading the severity of the neuropathies was accomplished by using a concurrent test grade change, a convergent test grade change, a divergent test grade change, and a no test grade change. These measures were compared to those taken a year later. The authors reported that CPT and NCS were highly correlated but that CPT was more sensitive. Details of clinical diagnosis, clinical examinations, and testing conditions were not provided. There was also no discussion of clinical utility.

Menkes (2000) evaluated CPT as an adjunctive test for detection of acquired demyelinating polyneuropathies.[6] The authors used normative data previously established for absolute CPT, side-to-side CPT ratios, and intrasite CPT ratios between different frequencies in order to determine if CPT testing can be used to diagnose demyelinating polyneuropathies. Ten patients with demyelinating polyneuropathies and 10 patients with axonal polyneuropathies were recruited. Diagnosis of demyelinating polyneuropathy was based on the presence of two of the three following criteria: (1) clinical profile; (2) cerebrospinal fluid profile; and (3) NCS profile. Additional inclusion criteria for axonal polyneuropathy were based on NCS and EMG profiles. Ages ranged from 41-78 years. The technologist using the CPT was blinded to the study hypothesis and the patients' diagnoses. C2 spinal nerve distribution, lateral antebrachial cutaneous nerve distribution, and sural nerve distribution were examined. The authors reported that CPT detected demyelinating polyneuropathies with 50% sensitivity and 100% specificity. They also stated that the diagnostic sensitivity was similar to those of other published diagnostic criteria. The diagnostic sensitivity of CPT testing for axonal polyneuropathies was reported as 70%. The authors concluded that CPT should be considered an adjunctive test to NCS and EMG in the diagnosis of demyelinating polyneuropathies. However, all patients in the study were diagnosed without using CPT. Also, the authors assert that CPT has similar sensitivity to other electrodiagnostic tests.

Katims (1989) studied 29 dialysis patients and compared the screening and evaluation of carpal tunnel syndrome by CPT to NCS.[7] Patients completed a questionnaire to identify symptoms of carpal tunnel syndrome (CTS). CPT was performed on the median, ulnar, and peroneal nerves during hemodialysis. CPT measurements were graded into classes of severity. CTS was diagnosed using CPT by determining the difference between the CPT grades from median and ulnar nerves in the same hand. NCS was only performed on the ulnar nerve if CTS was suspected. The authors reported that the "overall severity of the neuropathy detected by both tests from the median and peroneal nerves combined was highly correlated, $r = 0.79$ ($p < 0.001$). CPT yielded greater overall levels of detection sensitivity for neuropathy (92%) than did [NCS] (79%) for the medial and peroneal nerves combined." The authors conclude that the study supports previous findings that "CPT is sensitive for quantitatively evaluating the integrity of sensory afferents and is significantly correlated with [NCS] findings." In addition, CPT is diagnostic for CTS.

Katims (1986) performed CPT on 44 normal subjects and 33 diabetic patients.[8] A limited neurological examination was also performed to determine the presence of peripheral neuropathy. Although not stated, it may be inferred that all the diabetic patients had evidence of neuropathy on clinical examination. The authors reported a sensitivity of 94% for detecting neuropathy in the diabetic patients when the detected abnormal measurements from the 5 Hz and 2000 Hz frequencies for the three body locations tested (face, index finger, great toe) were combined. Although CPT typically includes the use of 250 Hz stimuli, the article did not state whether or not such stimuli were used, and, if so, what results were obtained. CPT in the normal subjects without clinical evidence of neuropathy varied significantly with age as well as the frequency and location of the stimulation. Because all patients presumably had signs of neuropathy on physical exam, but not all patients were diagnosed as having neuropathy based on CPT measurements, it is unclear from this study if CPT is more sensitive than a physical exam in detecting diabetic sensory peripheral neuropathy.

Masson (1989) performed a retrospective study that analyzed the use of CPT for the assessment of peripheral neuropathy in patients with type I or type II diabetes and then compared it to more traditional methods of quantifying nerve function.[9] The authors recruited 31 healthy control subjects and 90 diabetic patients with type I or type II diabetes mellitus, with and without neuropathy to participate in the study. The participants were divided into 4 groups. The control group was group 1 while groups 2, 3, and 4 were composed of diabetics without neuropathy, diabetics with neuropathy, and diabetics with neuropathic ulcers, respectively. The study did not report how the presence or absence of neuropathy was determined. A cohort of 68 patients also had conventional assessment of peripheral nerve function, using a biothesiometer for the measurement of vibration perception threshold, a thermoaesthaesiometer for the measurement of warm thermal discrimination threshold, and peroneal motor conduction velocities. Ages ranged from 19-82 years. CPT measurements were significantly different between the neuropathy group versus the control group; the neuropathic ulcer group was also statistically different than the control group as well as the diabetics without neuropathy group. The authors reported statistically significant Spearman correlation coefficients (0.34 to 0.46) between 5 Hz and 250 Hz and thermal threshold, and between 2000 Hz and vibration perception threshold (0.42 to 0.69) and peroneal motor conduction velocity (-0.66). Sensory nerve conduction measurements were not reported. The authors state that these correlations suggest that CPT can provide information about the functional integrity of different fiber types. However, the authors point out that CPT may not directly stimulate nerve fibers but, instead, produce different sensations due to differential responses of cutaneous mechanoreceptors.

Ro (1999) performed CPT on patients with Fabry's disease.[10] These individuals are afflicted with an X-linked disorder caused by a deficiency of the lysosomal enzyme alpha-galactosidase A. The accumulation of glycolipids in dorsal root ganglia is responsible for the episodic burning pain and constant acroparesthesias experienced by these patients. Nerve biopsy specimens taken from these patients usually show loss of small myelinated and unmyelinated fibers. The study was designed to assess subjective complaints of pain and paresthesias as well as to compare the values of CPT and correlate NCS in detecting the sensory neuropathy. Sixteen patients from the same family (8 hemizygous men and 8 heterozygous women) were recruited for the study. Fifty healthy subjects were used as controls. All patients reported symptoms of neuropathic pain. They received a symptomatic score based on their self-graded symptoms. CPT was performed in the median and peroneal nerve distributions for all three stimuli (6 measurements). The locations for conducting NCS were not reported. All 16 patients had normal NCS. Abnormal findings using CPT were reported for 5 Hz (6 of 16, 37.5%), 250 Hz (8 of 16, 50%), but not 2000 Hz (0 of 16, 0%). The authors reported that the results showed CPT testing at low frequencies were significantly more sensitive than at a higher frequency and more sensitive than NCS in detecting sensory neuropathies in patients with Fabry's disease, $p < 0.001$. There was no correlation between CPT testing and clinical symptom scores, duration of disease, creatinine clearance values or *a*-galactosidase A activities in either hemizygous or heterozygous patients.

Cheng (1999) studied 558 non-insulin dependent diabetics for the purpose of identifying risk factors for diabetic peripheral sensory neuropathy in type 2 diabetes.[11] Patients were administered the following tests: monofilament testing, graduated tuning fork, and CPT. Those patients who had two or more abnormal quantitative sensory testings were defined as having diabetic sensory neuropathy. Of the 558 patients, 62 were classified as having neuropathy. Symptoms and findings on physical examination consistent with neuropathy were not reported. NCS was not performed.

Lerner (2000) evaluated the reliability and reproducibility of sNCT in establishing normative values for evaluation at the mental foramen area.[12] The authors examined 34 healthy subjects who were tested twice over several days with sNCT. On the left side, the test showed no difference between the first and second test ($p > 0.05$). On the right side, there was a statistical difference between the first and second test for all three frequencies, but the confidence interval was very narrow and the differences were not clinically significant. The study also found significant differences between the left and right sides. The authors concluded that sNCT is a reliable method to quantify sensory nerve function in the mental foramen area in healthy subjects.

Rendell (1989) attempted to determine how useful CPT might be for assessing diabetic sensory neuropathy.[13] The purpose of the study was to determine if CPT could map the extent of sensory neuropathy. Forty-four non-diabetic volunteers and 59 diabetic patients were subjected to a detailed clinical neurological examination consisting of questions regarding symptoms and a physical evaluation. An assessment of light touch, pain, vibratory, and thermal sensation was performed on each individual's hand, wrist, elbow, foot, ankle, and knee. The results of these tests yielded a symptom score and a physical score. An examiner blinded to the results obtained from the clinical neurological examinations performed CPT evaluations on all subjects at sites identical to those used for light touch, pinprick, and thermal physical testing. CPT correlations with the physical score gave r values of 0.55 for 5 Hz, 0.60 for 250 Hz, and 0.62 for 2000 Hz. CPT correlations with the symptom score were not as strong. Correlation coefficients were 0.45 for 5 Hz, 0.46 for 250 Hz, and 0.51 for 2000 Hz. The symptom and physical scores, however, were not independently validated. Patients with diabetic neuropathy showed higher CPT values than non-diabetic volunteers and diabetics without neuropathy as revealed by physical examination. CPT measures were normal in diabetic patients without clinical evidence of neuropathy. The authors conclude that CPT "appears to be a useful technique for assessment of diabetic sensory neuropathy."

Technology Assessments

In 1999, the American Association of Electrodiagnostic Medicine (AAEM) published a technology review of the Neurometer Current Perception Threshold.[14] The opinions stated in the assessment, however, may reflect those of the author and not necessarily of the Association.

The summary of the literature was presented in the form of general and specific issues followed by various recommendations.[15] Most of the published articles were studies correlating the performance of the CPT to results obtained from standard nerve conduction studies within populations of affected individuals with known diseases. According to the technology assessment the fundamental problem is the absence of an appropriate standard against which to measure CPT. Another problem with the technique is that it elicits multiple measures, and any abnormality detected is considered significant. Also, there is a tendency in the literature to arbitrarily assign various degrees of deviation from a normal population as grades of severity, with little additional information given. The technology assessment also concluded that "CPT provides only one set of values for each site studied, unlike nerve conduction studies which provide more information. Therefore, the location and type of peripheral nerve pathology is less clear with CPT testing."

The report made the following *recommendations*:

"Determination of current perception threshold has the potential for evaluation of patients with peripheral nervous system diseases resulting in altered cutaneous sensation. This type of testing could potentially complement needle EMG and nerve conduction studies, to assist with evaluating treatment response or disease progression after a diagnosis is made. However, conflicting information and methodological problems exist regarding the utility of the Neurometer CPT for the diagnostic evaluation of specific disease conditions. Future research is needed to establish statistically expressed normal values and to demonstrate the sensitivity and specificity of the Neurometer CPT data."

Position Statements

We have not identified any position statements by medical professional societies on sNCT. In addition, we have not found any professional guidelines relating to the use of this technology. However, the American Association of Clinical Endocrinologists wrote to CMS on November 26, 2001 in support of Medicare coverage of sNCT. The Association believes that it is reasonable to perform sNCT in some diabetic patients, because it may detect neuropathy earlier than NCS (e.g., identified hyperesthesia) and could be used for monitoring improvement or worsening of diabetic polyneuropathy. The Texas Worker's Compensation Commission also wrote to CMS on September 12, 2001 decision:

"The Spine Treatment Guideline Revision Workgroup review of CPT, a type of sensory conductive test, indicated that there was supporting literature for its effectiveness in some medical conditions but that there was little evidence to warrant its use for musculoskeletal conditions. However, staff's review of the literature supplied by commenters supported the efficacy for CPT testing for peripheral neuropathy that is not clinically detectable through sensory nerve conduction velocity (NCV) studies. Staff's review of the literature also supported the efficacy of CPT testing for the evaluation of radiculopathies and as an appropriate diagnostic tool for the quantitative measure of the functional integrity of sensory nerve fibers..."

We also contacted experts in the field of neuropathies. The experts were uniformly unaware of a use for sNCT that would alter patient management.

CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular items or service is covered nationally under title XVIII of the Social Security Act. § 1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, in general, the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." § 1862(a)(1)(A).

CMS has issued regulations pertaining to the coverage of diagnostic tests under the part B program. Those rules provide that, except for a few exceptions, diagnostic tests must be ordered by the physician who treats the beneficiary for a specific medical problem and the physician must use the results in the management of the beneficiary's specific medical problem. 42 C.F.R. § 410.32. In general, tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary. See also 42 C.F.R. § 411.15(k)(1).

As described below in this decision memorandum, we have fully examined the medical and scientific evidence submitted with the request for a national coverage decision, as well as the additional information obtained as a result of our own investigation. We have determined that the available evidence is not adequate to reliably conclude that sNCT is reasonable and necessary for the diagnosis of sensory neuropathies because it is not clinically effective. Therefore, we intend to issue a national noncoverage decision.

There is no gold standard for the evaluation of sensory nerve function. The most commonly used electrodiagnostic test is NCS. The principal limitation of NCS is that it measures velocity and amplitude only in the largest diameter and fastest conducting nerve fibers. It provides no information on the integrity of small- and medium-sized fibers. In addition, there is a wide range of normal values. A patient may have a drop in conduction velocity yet still fall within the normal range. Therefore, some patients with dysfunction of sensory nerves may not be detected using NCS.

sNCT reportedly assesses large, medium, and small fibers and does not cause the discomfort that may be experienced with NCS. Of note, sNCT bypasses some of the sensory receptors (e.g., Meissner's corpuscles, Pacinian corpuscles) and the sensations perceived by the subject are not those of normal sensation (e.g., heat, cold, touch, pain). The principal limitations of sNCT are the following: (1) it can only be performed on patients with normal attention and other cognitive abilities, as well as intact central nervous system sensory processing, because test results are based on the patient's ability to detect and report his or her perception of the administered stimuli; and (2) unlike NCS, sNCT does not assess the function of motor nerves. sNCT also measures responses to three different stimulus intensities. The greater number of measurements obtained with sNCT than with NCS may increase the likelihood of reporting an abnormal value. This is particularly problematic when the study population is determined to have a neuropathy using another testing modality, such as a physical examination. This may lead to the reporting of a higher sensitivity, but a lower specificity due to a higher number of false positives.

In our review of the literature we did not find any studies on the effect of sNCT on patient management. Only four studies compared sNCT to NCS. Each study had serious methodological flaws and specificity often was not or could not be determined. In general, the studies evaluated a small number of subjects and none masked the individuals performing the electrodiagnostic studies. Only the Rendell study reported detailed inclusion and exclusion criteria. Therefore, these studies may have produced biased results.

Rendell (1989) calculated Spearman correlation coefficients for NCS and sNCT with a symptomatic score and a physical score in patients with diabetes. Both scores as well as the classification of severity of neuropathy were not independently validated. A direct comparison between NCS and sNCT was not performed nor was a correction for multiple statistical analyses conducted. Therefore, the study is not adequate to demonstrate the relative accuracy of NCS and sNCT in assessing diabetic sensory polyneuropathy. Moreover, the diagnosis of neuropathy was based on history and physical examination, raising into question whether sNCT is more accurate in diagnosing diabetic polyneuropathy than a history and physical examination.

Weseley (1988) performed NCS and sNCT in dialysis patients and then graded measurements based on a classification system that was not independently validated. sNCT and NCS were not performed at the same time and greater abnormal findings on sNCT may have resulted from performing the test concurrently with dialysis. Physiological and physical changes during dialysis may affect a patient's ability to accurately detect test stimuli as well as nerve function. Also, sensitivity was based on the relative ability of each test to report an abnormal result consistent with a neuropathy in each patient. However, the use of an independent indicator of neuropathy was not reported. Instead, patients were assumed to have a neuropathy based on test measurements. Therefore, it is unclear if any of the patients had a neuropathy. Specificity was not reported. Finally, the authors did not perform a statistical comparison between NCS and sNCT. Therefore, the study is not adequate to demonstrate the relative accuracy of NCS and sNCT in assessing uremic neuropathy.

Katims (1989) performed NCS and sNCT in dialysis patients to assess these tests as screening measures for carpal tunnel syndrome (CTS) in uremic patients. The grading system and CTS questionnaire used in the study were not independently validated. Twelve subjects reported symptoms of CTS. NCS identified CTS in three of these subjects. sNCT identified CTS in five of these patients, but also identified CTS in two patients without symptoms of CTS. NCS did not identify any patients as having CTS who did not have symptoms. If the questionnaire used is an independent measure of CTS, sNCT may have a high false positive rate. This is consistent with the above observation that multiple measurements would result in a higher sensitivity but a lower specificity than NCS. Furthermore, although the authors reported that sNCT had a greater sensitivity than NCS for the median and peroneal nerves combined, which was not the main objective of the study, the comparison was not based on an independent measure of a neuropathy and a statistical comparison of sNCT and NCV was not performed. Therefore, the study is not adequate to demonstrate the relative accuracy of NCS and sNCT in assessing uremic neuropathy.

The study by Ro (1999) on patients with Fabry's disease suggests that sNCT may be more sensitive than NCS in detecting neuropathy in patients with Fabry's disease. This is of questionable clinical utility in the Medicare population since the symptoms of Fabry's disease often begin in childhood and are typically diagnosed by early adulthood. The study also suggests that sNCT may distinguish between sensory fiber types and may be more sensitive than NCS in detecting sensory neuropathies that affect only small myelinated and unmyelinated fibers. However, the patient population tested in this study was small (only 16 patients) and the symptoms scores were not independently validated.

In summary, the available scientific evidence is not adequate to demonstrate the accuracy of sNCT or the accuracy of sNCT as compared to NCS. Unlike NCS, sNCT does not assess the integrity of motor nerves, which is important in evaluating some patient populations, such as diabetics. In addition, it is not evident that sNCT offers any diagnostic advantages over a history and physical examination in detecting the presence of a neuropathy. There are also no clinical studies that we identified that demonstrate that the use of sNCT leads to changes in patient management in a particular Medicare subpopulation. As stated in 42 C.F.R. § 410.32, a diagnostic test is not reasonable and necessary unless its results are used by the treating physician (who also orders the test) in the management of the beneficiary's specific medical problem. In our discussions with experts, we were also unable to identify a subpopulation in whom the results of sNCT would alter medical care. Although the Association of Clinical Endocrinologists believe that sNCT is useful to detect sensory neuropathies in some diabetic patients, we were unable to establish the specific changes in patient management that would occur with its use. Moreover, the potentially lower specificity of sNCT as compared to NCS may lead to the administration of unnecessary and possibly harmful treatments. Therefore, CMS concludes that the use of sNCT in the diagnosis of sensory neuropathies is not reasonable and necessary. However, we believe that sNCT merits further study and we encourage investigators to conduct well-designed clinical trials to demonstrate the clinical effectiveness of the test.

DECISION

CMS concludes that the scientific and medical literature do not demonstrate that the use of sNCT to diagnose sensory neuropathies in Medicare beneficiaries is reasonable and necessary. Therefore, we intend to issue a national noncoverage decision.

1 All three tests are not necessarily equivalent in the type of information they give, and therefore are not presumed to necessarily be substitutive.

2 The terms Current Perception Threshold (CPT) and sensory nerve conduction threshold (sNCT) are used interchangeably in this memorandum.

3 Specificity is used to rule in disease, whereas high sensitivity rules out disease.

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7 Katims JJ, Rouvelas P, Sadler BT, Weseley SA. Reproducibility and comparison with nerve conduction in evaluation of carpal tunnel syndrome. *Trans Am Soc Artif Intern Organs* 1989;35:280-284.

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11 Cheng W, Jiang Y, Chuang L, et al. Quantitative sensory testing and risk factors of diabetic sensory neuropathy. *Journal of Neurology* 1999;246:394-398.

12 Lerner TH, Goldstein GR, Hittelman E. Quantitative sensory nerve conduction threshold (sNCT) evaluation of the trigeminal nerve at the mental foramen area. *Journal of Prosthetic Dentistry* 2000;84:103-107.

13 Rendell MS, Dovgan DJ, Bergman TF, et al. Mapping diabetic sensory neuropathy by current perception threshold testing. *Diabetes Care* 1989;12:636-640.

14 American Association of Electrodiagnostic Medicine. Technology review: the neurometer current perception threshold. *Muscle Nerve* 1999;22:523-531.

15 The manufacturers took issue with many aspects of this report and wrote a detailed response, with the matter currently in litigation.

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